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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/021,660	02/10/1998	MARGARET H. BARON	1874/110	4751

28120 7590 01/17/2003

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BOSTON, MA 02110-2624

EXAMINER
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SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/17/2003

45

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/021,660

Applicant(s)

BARON ET AL.

Examiner

Lorraine Spector

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57-73 and 82-144 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-73 and 82-144 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/02 has been entered.

Claims 57-73 and 82-144 are under consideration.

***Specification***

The amendment filed 8/27/01 remains objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The sequences and description of sequence properties added from WO 95/18856 represent new matter because they were added by improper incorporation by reference (see above). The description of % identity or homology to sequences and hybridization as newly set forth is also new matter. (See previous Office action, paragraph bridging pages 3-4.) This rejection is maintained for reasons of record in paper number 36, mailed 4/23/02 and paper number 38, mailed 7/18/02.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 57-73 and 82-113 remain, and newly introduced claims 82-144 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office action, paper number 34, on page 4, and as discussed in the sections entitled "Incorporation by Reference". .) This rejection is maintained for reasons of record in paper number 36, mailed 4/23/02 and paper number 38, mailed 7/18/02.

Claims 57, 58, 60-73 and 82, 83, 85-96 and 99-113 remain, and newly introduced claims 114, 117-132, and 134-144 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of stimulating a population of undifferentiated mammalian mesodermally derived cells to undergo hematopoiesis or of stimulating hematopoiesis in an animal, comprising contacting said cells or administering to the animal, respectively, an effective amount of Ihh, Dhh or Shh protein or a fragment thereof which binds to patched and induces cells to undergo hematopoiesis such that the protein or fragment thereof contacts or would reasonably be expected to contact undifferentiated mammalian mesodermally derived cells or hematopoietic stem cells, does not reasonably provide enablement for administration wherein the protein or fragment thereof does not specifically contact the above cell types and wherein the protein or fragment is not Ihh, Dhh, Shh or a fragment thereof which binds to patched and induces cells to undergo hematopoiesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons set forth in the previous Office action, paper number 36, on pages 4-7.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-73 and 82-144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57, 83, 88, and 96 have been amended to recite that the polypeptide "is functionally equivalent to a naturally occurring hedgehog protein". The Examiner interprets this limitation as meaning that the polypeptide has equivalent function to at least one naturally occurring hedgehog protein. To determine such, one would be required to have in hand all possible naturally occurring hedgehog proteins. As the activities of all naturally occurring hedgehog proteins have not been described, nor have the proteins themselves, one of ordinary skill in the art would not be able to determine whether a polypeptide did or did not meet the limitations of the claims. Further, it is not clear what the metes and bounds of "functionally equivalent" are in this circumstance, as no function is specified, and as there are numerous embodiments that would retain hematopoietic activity, while having other functions (antigenicity, for example) altered as compared to a naturally occurring hedgehog protein. Accordingly, the metes and bounds of the claims cannot be determined.

The newly introduced claims, such as claims 114, 132, 137 and 144, all use 'means plus function' language rather than specifically referring to the active agent. Applicants are correct in their assertion that means plus function language is permissible under 35 U.S.C. §112, sixth paragraph, and that such must be interpreted in view of the means disclosed in the specification as originally filed. However, even though that is the case, the means plus function language renders the claims indefinite because the language does not appear in the specification

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as originally filed, which accordingly cannot be looked to to breath life and meaning into the term with regards to its intended scope. Specifically, with respect to "means for activating hedgehog signaling", two possible interpretations of the language are (1) that applicants intend "means" to indicate hedgehog proteins and derivatives thereof, as set forth in the specification; if this is the case, then it may well be that the claims are unnecessarily duplicative of other pending claims, or otherwise that, as set forth at page 26 of the specification, the claims encompass any functional equivalent of a hedgehog protein. An alternative interpretation is that (2) the "means" intends *anything* that has been disclosed that would achieve the desired function, including proteins, nucleic acids, cells, etc. (see for example page 26 of the specification). This latter interpretation encompasses any functional equivalent of a hematopoietic hedgehog protein, which would raise new questions of enablement and written description under 35 U.S.C. §112, first paragraph. In either case, the metes and bounds of the claims cannot be determined. Similar problems apply with respect to "means for binding patched and thereby activating hedgehog signaling". Further, it is not clear how "means for activating hedgehog signaling" differs from to "means for binding patched and thereby activating hedgehog signaling", as the specification discloses no means for doing one without also doing the other. Finally, claims reciting to "means for binding patched and thereby activating hedgehog signaling" are incomplete, as not all agents that bind patched will activate hedgehog signaling (binding is not sufficient to induce activation).

Claims which recite "human progenitor cells", such as claims 91 and 140, are indefinite because it is not clear to what cells such refers. It is not clear whether the cells are progenitors

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*of humans, or alternatively whether the cells are progenitor cells (and if so, what kind) obtained from a human.*

Claims that state the “the cells comprise embryonic tissue”, such as (but not limited to) claim 107, are indefinite as tissues comprise cells, and not the other way around. Similarly, it is not clear how cells can “comprise an embryonic explant culture”, as recited for example in claim 108, nor is it clear how an explant “culture” can be a single blastocyst, as recited for example in claim 109.

The remaining claims are rejected for depending from an indefinite claim.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

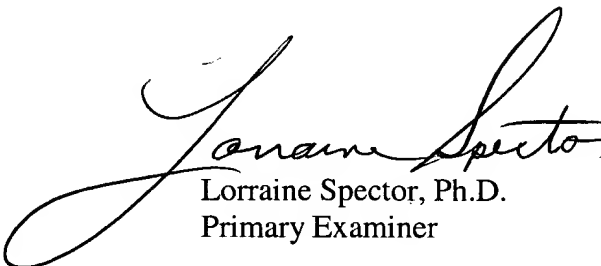
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.



Lorraine Spector, Ph.D.  
Primary Examiner